

**REMARKS**

Claims 1-66 are pending in the application. Of these, Claims 1-26 and 53-66 are withdrawn from consideration. Claims 27-52 stand rejected.

**35 U.S.C. 102 Rejections**

Claims 27 and 52 stand rejected under 35 U.S.C. 102(b) as being anticipated by Virtanen *et al.* (U.S. Pat. No. 6,402,919, hereinafter "Virtanen").

Claim 27 as originally filed recites in part:

a controller operatively coupled to the input valve and including executable instructions to convert and execute operational input to control the valve for providing a sample of the liquid source to the capillary electrophoresis column.

MPEP 2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Regarding Claim 27, the non-final Office Action of August 15, 2008 stated at page 3, line 3 that the foregoing elements of Claim 27 are "implied" by Virtanen at col. 3, lines 36-37, which discloses, "Operation of [Virtanen's] entire apparatus can be controlled by means of a micro-processor." Thus, the Office Action of August 15, 2008 acknowledged that Virtanen does not expressly teach "operational input" of Applicants' Claim 27.

Applicants will first show below that the foregoing elements of Claim 27 are not inherently described and that one of ordinary skill in the art would not draw the implication mentioned above in the Office Action.

Furthermore, MPEP 2121 states:

A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention ... (*Impax Labs. Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1383, 81 USPQ 2d 1001, 1013 (Fed. Cir. 2006))

The CAFC decision cited in the foregoing MPEP section states, "Prior art is not enabling so as to be anticipating if it does not enable a person of ordinary skill in the art to carry out the invention." Furthermore, in an opinion citing *Impax Labs Inc. v. Aventis, Pharm Inc.*, the CAFC stated in *In re Martin Gleave and Maxim Signaevsky* (CAFC 2008-1453):

A reference is anticipatory under § 102(b) when it satisfies particular requirements. ... [T]he reference must "enable one of ordinary skill in the art to make the invention without undue experimentation."

Applicants will show below that Virtanen does not enable a person of ordinary skill in the art to make Applicants' invention as described above.

1. *Virtanen does not inherently describe the elements of Claim 27 that are not expressly described.*

The non-final Office Action stated that Virtanen discloses the foregoing elements of Claim 27 related to converting and executing operational input impliedly based on the single sentence "Operation of [Virtanen's] entire apparatus can be controlled by means of a micro-processor." The final Office Action states that the foregoing statement of Virtanen implies various intermediate level processing between the stage of user input and the binary code handled by the microprocessor.

However, Applicants' claimed invention as in Claim 27 exceeds the scope of what would be found inherently at an intermediate stage of processing in a controller for an apparatus such as Virtanen's. Virtanen's apparatus, in order to be controlled by a microprocessor, would undoubtedly require additional electronic components than just a microprocessor. However, Virtanen, by providing only a single sentence directed to such a controller, leaves unclear exactly which additional components would be needed, or for what specific functionality. Applicants respectfully submit that it is improper to draw from Virtanen's single broad statement an implication that Virtanen impliedly teaches "a controller ... including executable instructions to convert and execute operational input" as in Applicants' Claim 27 (emphasis added). At most, a standard implementation according to the principles of automatic control (e.g., using a microprocessor) would enable execution of input data. An example of Applicants' "operational

input” may be in the form of an English-like pseudolanguage, as seen in the Specification as originally filed at page 32, lines 1-20).

According to [www.dictionary.com](http://www.dictionary.com), the word “inherent” means “existing in someone or something as a permanent and inseparable element, quality, or attribute” (emphasis added). Conversion of operational input as in Applicant’s Claim 27 is not inherent to a controller implementation of Virtanen’s apparatus, since such conversion is not an inseparable element of the implementation. One may implement a controller that performs standard controlling functions (e.g., for automation), without converting and executing operational input; in fact, an implementation without such elements would be standard practice. The Declaration under 37 C.F.R. 1.132 submitted concurrently herewith describes such a standard (“turnkey”) implementation. Absent any other guidance in Virtanen, it is improper to conclude that sophisticated intermediate level processing as in Applicant’s claimed invention would be inherent to Virtanen.

The Final Office Action states, at page 2, section 2, that Virtanen teaches adjusting, controlling, and modifying certain parameters. The Office Action refers to these actions in Virtanen as “operations” (emphasis in Office Action) and further refers Virtanen’s Claim 5, which recites “pumps ... operatively connected with ... solution reservoirs” (emphasis in Office Action). The Office Action apparently construes such teachings of operations and operatively connected pumps as equivalent to Applicants’ “operational input” as in Claim 27. Applicants respectfully disagree and submit that the mere use of the word “operatively” by Virtanen, in conjunction with “adjusting,” “controlling,” and “modifying,” does not mean that Virtanen teaches “converting and executing operational input.”

At most, disclosure by Virtanen of adjusting, controlling, and modifying teaches an ability on the part of a user to vary input parameters. Such teaching still refers to turnkey systems in which a user may turn a dial to a particular level (thus modifying a parameter) and then pressing a button to initiate operation. Thus, such teaching by Virtanen is patentably distinct from “converting and executing operational input,” which involves more sophisticated processing at an intermediate stage than Virtanen teaches or suggests.

2. *Virtanen does not enable a person of ordinary skill in the art to make Applicants' claimed invention.*

The implications described above (i.e., that Virtanen would have such additional elements regarding Applicants' Claim 27 that are not expressly disclosed) are not clear to a chemist, who is the relevant person of ordinary skill in the art of capillary electrophoresis (the relevant art in the context of embodiments of the present invention). In other words, although the Office Action states that intermediate processing components are allegedly inherent in Virtanen's invention (albeit only implicitly), a person of ordinary skill would not be skilled in electronic devices and electronic processing and would not be enabled, based on Virtanen, to design a system to "convert and execute operational input" as in Claim 27 (emphasis added). The Declaration under 37 C.F.R. 1.132 submitted concurrently herewith provides further support for this argument. The Declaration states that a person of ordinary skill would seek a turnkey solution that would lack elements of Claim 27, e.g., "executable instructions to convert and execute operational input."

Since Virtanen does not expressly or impliedly teach all the elements of Applicants' Claim 27, and since Virtanen does not enable one of ordinary skill to make Applicants' claimed invention as in Claim 27, Applicants respectfully submit that the rejection of Claim 27 under 35 U.S.C. 102(b) is improper and should be withdrawn.

Claim 52 recites similar patentably distinguishing elements as Claim 27. Claim 52 and all claims depending from Claims 27 and 52 should be allowed for at least the same reasons presented above.

### **35 U.S.C. 103 Rejections**

Claims 28-52 stand rejected under 35 U.S.C. 103(b) as being unpatentable over Virtanen in view of other references.

Dependent claims 28-38 inherit the foregoing patentably distinguishing elements of Claim 28 and should be allowed for at least the same reasons presented above.

Claims 39, 40, 49, and 51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen. The Office Action states that the elements of Claim 39 (e.g., regarding

“converting and executing operational input”) would have been obvious because of Virtanen’s statement that “Operation of the entire apparatus can be controlled by means of a microprocessor.” As previously stated regarding 35 U.S.C. 102 rejections, it would not have been obvious to a person of ordinary skill (i.e., a chemist) to “convert[] and execut[e] operational input” on the basis of that single broad sentence. Therefore, Applicants respectfully submit that the rejection of Claims 39, 40, 49, and 51 under 35 U.S.C. 103(a) is improper and should be withdrawn.

Claims 28-34 and 36 stand rejected under 35 U.S.C. 103(a) as being obvious over Virtanen in view of Nikiforov *et al.* (U.S. 7,060,171, hereinafter “Nikiforov”). Applicants respectfully disagree.

MPEP 2143 states that the Graham factors relevant to an obviousness determination (e.g., regarding obviousness to combine references) must be considered in the context of a person of ordinary skill in the art. On a related note, MPEP 2141.03 states:

The examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. (emphasis added)

Based on the foregoing MPEP sections (2143 and 2141.03), there is lack of motivation to combine Virtanen and Nikiforov in the context of Claims 28-34 and 36. As stated previously, the relevant person of ordinary skill for the present inquiry is skilled in the art of capillary electrophoresis. Such a person would not turn to the teachings of Nikiforov regarding interpreters for use in a capillary electrophoresis system to implement a sophisticated intermediate layer of processing between an end-user and a microcontroller.

Instead, such a person would seek a conventional automation technique, e.g., involving a microprocessor, as suggested by Virtanen. Such a “turnkey” solution for automation would enable an end user (a chemist skilled in capillary electrophoresis but not in computer programming, computer systems, or automated systems) to operate a capillary electrophoresis system by turning a key, pressing a button, or performing other simple steps to operate valves and equipment. Such a technique might enable modifying parameters in a simple way (as in Virtanen) but would not include sophisticated intermediate processing that includes an interpreted language or related computer programming techniques (as in Nikiforov). In other

words, the arts of computer programming and interpreted languages are "remote" with respect to capillary electrophoresis in the context of MPEP 2141.03, and it would not have been obvious to one of ordinary skill in the art (of capillary electrophoresis) to combine Virtanen and Nikiforov in the context of Applicants' claimed invention.

Because there is no basis for combining or modifying the cited references, Applicants submit that the resultant combination is not obvious. Accordingly, Claims 28-34 and 36 are not obvious in view of the cited references.

Furthermore, Claims 37 and 50 are additionally patentable at least for reciting "detect[ing] errors in the operational input." Sarrine (U.S. Pat. No. 5,147,522, hereinafter "Sarrine") was introduced as a secondary reference in the obviousness rejection of these claims. The non-final Office Action states, at page 19, line 14, that Sarrine discloses an automatic electrophoresis apparatus and control having "an input signal regarding the alignment of the sample source. The automation means is configured to detect an error in this signal." However, Sarrine's error detection of an input signal is patentably distinct from error detection of "operational input" as in Applicants' amended Claim 27. Sarrine's error detection is of the kind conventionally found in automation systems, e.g., turnkey systems as in the discussion above about a person of ordinary skill being a chemist.

The other references cited in the rejections of Claims 37 and 50 respectively, do not cure the foregoing deficiency of Sarrine. Therefore, Applicants respectfully submit that the rejection of Claims 37 and 50 under 35 U.S.C. 103(a) is improper and should be withdrawn.

#### **Declaration Under 37 C.F.R. 1.132**

A declaration under 37 C.F.R. 1.132 is provided by George E. Barringer, Jr., who is a person of ordinary skill in the art of capillary electrophoresis.

Under MPEP 716, Applicants are herein submitting a Rule 1.132 declaration of George E. Barringer, Jr., who is a person of ordinary skill in the art of capillary electrophoresis with over 20 years of experience in the art. When any claim of an application rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under MPEP 716. Applicants respectfully request that

the Office review the 37 C.F.R. 1.132 declaration, consider the evidentiary proof of the declaration, and enter the declaration into the record. Applicants submit to the Office that the declaration submitted under 37 C.F.R. 1.132 is responsive to the rejection and presents sufficient facts to overcome the rejections.

The declaration is directed to the rejection of Claim 27 under 35 U.S.C. 102 based on Virtanen. The declaration addresses Claim 27 in the context of Virtanen and establishes that 1) a person of ordinary skill in the context of the presently claimed invention is a chemist; and 2) processing that includes "convert[ing] and execut[ing] operational input" as in Claim 27 is not inherent or obvious in the context of conventional capillary electrophoresis systems and/or Virtanen, i.e., is not obvious to a person of ordinary skill in the art (thus addressing the rejection of Claim 39 under 35 U.S.C. 103 as well).

### CONCLUSION

In view of the above amendments and remarks, it is believed that all pending claims (Claims 27-52) are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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